

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 68911-061	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/US03/33362	International filing date (day/month/year) 20 October 2003 (20.10.2003)	Priority date (day/month/year) 21 October 2002 (21.10.2002)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61K 35/78 and US Cl.: 424/773, 778		
Applicant METAPROTEOMICS, LLC.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of ___ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of report with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability, citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 21 May 2004 (21.05.2004)	Date of completion of this report 05 September 2005 (05.09.2005)
Name and mailing address of the IPEA/US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (703) 305-3230	Authorized officer Cybille Delacroix-Murheid Telephone No. 571-272-0572

Form PCT/IPEA/409 (cover sheet)(July 1998)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US03/33362**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

Novelty (N)	Claims <u>1-235</u>	YES
	Claims <u>NONE</u>	NO
Inventive Step (IS)	Claims <u>1-119, 158, 212-235</u>	YES
	Claims <u>120-157, 159-211</u>	NO
Industrial Applicability (IA)	Claims <u>1-235</u>	YES
	Claims <u>NONE</u>	NO

2. CITATIONS AND EXPLANATIONS

Claims 120-157, 159-211 lack an inventive step under PCT Article 33(3) as being obvious over Kuhrts and Sreenivasan et al. and Barney et al.

Kuhrts discloses methods of providing anti-inflammatory and pain relieving action in a patient in need thereof. Specifically, Kuhrts discloses administering to the patient suffering from osteoarthritis, rheumatoid arthritis or acute pain a composition containing a hops extract containing alpha and beta acids (lupulone, colupulone, adlupulone) in combination with glucosamine. The hops extract functions as a COX-2 inhibitor. Kuhrts also teaches that the phytoestrogens in hops have been shown to inhibit the growth of breast cancer cells. Please see [0015]-[0017]; [0041]-[0042].

Sreenivasan et al. disclose that lupulones, i.e. beta acids, derived from beer hops are effective anti-microbials. Please see column 1, lines 10-56.

Barney et al. disclose various hop acids as claimed by applicant wherein the hop acids are used to inhibit the growth of microorganisms that cause plaque or periodontal disease. Please see column 1, lines 35-52.

Kuhrts, Sreenivasan and Barney et al. do not specifically disclose the claimed dosage amounts or that the hops extract containing compositions contain compounds having the claimed formulae. However, the claimed formulae would be obvious in the prior art since the prior art discloses administration of substantially identical compositions containing hops extracts. Moreover, since dosage amount often correlate to therapeutic efficacy, it would have been obvious to one of ordinary skill in the art to further modify the methods such that the compositions containing the hop extract are administered at a dose that is effective to exert an anti-inflammatory or analgesic response.

Concerning claims drawn to modes of administration, i.e. oral, topical, etc., mode of administration is an art-recognized result effective variable and it would have been obvious to one of ordinary skill in the art to optimize them in the methods of the prior art.

Finally, inhibition of prostaglandin synthesis would have been obvious since the prior art disclose administration of substantially identical compositions to a patient.

Claims 1-235 meet the criteria set out in PCT Article 33(4), because the subject matter claimed can be made or used in industry.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US03/33362

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☒ the description:
pages 1-130 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the claims:
pages 131-170 as originally filed
pages NONE as amended (together with any statement) under Article 19
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☒ the drawings:
pages 1-14 as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____
- ☐ the sequence listing part of the description:
pages NONE as originally filed
pages NONE filed with the demand
pages NONE filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

- ☒ the description, pages NONE
- ☒ the claims, Nos. NONE
- ☒ the drawings, sheets/fig NONE

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.